UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GENZYME CORPORATION, Plaintiff, and ENDO PHARMACEUTICALS INC., Intervenor-Plaintiff, vs. SANDOZ, INC., Defendant.	Civil Action No. 09-cv-01750-JFM

ENDO PHARMACEUTICALS INC.'S
REPLY BRIEF IN FURTHER SUPPORT OF
GENZYME CORPORATION'S MOTION TO DISMISS
SANDOZ'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT
OF NONINFRINGEMENT AND INVALIDITY OF THE '780 PATENT

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The Federal Circuit's holding in Janssen Pharmaceutica, N.V. v. Apotex, Inc., 540 F.3d 1353 (Fed. Cir. 2008), requires that Sandoz's declaratory judgment counterclaims relating to the '780 patent be dismissed. In Janssen, the court held that no justiciable case or controversy exists when the harm being alleged by the later generic applicant flows directly (and only) from the 180-day exclusivity period to which the first generic applicant is entitled. This is precisely the case with Sandoz's alleged harm here.

Sandoz disingenuously asserts that Endo and Genzyme are acting to "stifle competition" by opposing Sandoz's counterclaims. In so doing, Sandoz mischaracterizes the important incentive of the 180-day generic exclusivity period. Congress enacted this marketing exclusivity period to incentivize generic applicants to initiate investment in developing new generic drugs and challenge patents. Congress provided this incentive to ensure expedient generic market entry across the industry. Having promptly asserted the first patent challenge to Renagel®, Endo earned the right to this exclusivity period. Sandoz should not be able to use this litigation to undermine the incentive structure enacted by Congress.

I. SANDOZ'S ALLEGED HARM DOES NOT CREATE A JUSTICIABLE ARTICLE III CASE OR CONTROVERSY

Both Sandoz and Endo have filed Paragraph III certifications to the Genzyme patents that expire on August 11, 2013 ("the 2013 patents"). FDA will therefore approve neither Sandoz's nor Endo's ANDA prior to that date. August 12, 2013 is the first date Endo can enter the market. Under the Hatch-Waxman framework, Sandoz's first possible entry date is 181 days after Endo launches its product. See 21 U.S.C. § 355(j)(5)(B)(iv)(I). Even if Sandoz were successful in its strategy to destroy Endo's 180-day exclusivity, it would not be able to bring a generic product to market before August 12, 2013.

The harm asserted by Sandoz is the alleged deprivation of the opportunity to market its product prior to Endo. (Sandoz Opp'n Br. at 20.) More specifically, Sandoz asserts that Endo's exclusivity may prevent it from entering the market until 2020, when Genzyme's '780 patent expires, and that Sandoz should be permitted to launch on the day after the 2013 patents expire. (Sandoz Opp'n Br. at 10, 1.) Under the Federal Circuit's holding in Janssen, 540 F.3d at 1361-63, Sandoz's alleged harm does not create a justiciable Article III case or controversy.

A. The Federal Circuit's Holding in *Janssen* Applies and Is Controlling

The harm asserted by Sandoz is identical to the harm considered and rejected by the Federal Circuit in Janssen. The court concluded that "Apotex's inability to promptly launch its generic risperidone product because of Teva's 180-day exclusivity period is not a cognizable Article III controversy, but a result envisioned by the Hatch-Waxman Act." Id. at 1361. Likewise, Sandoz's inability to enter the market immediately upon expiration of the 2013 patents because of Endo's 180-day exclusivity is precisely what Congress intended and "does not present a justiciable Article III controversy." Id. at 1362.

The holding in Janssen applies here as Sandoz is in exactly the same situation as Apotex (the later applicant in Janssen). Sandoz asserts that the holding does not apply because, unlike Apotex, Sandoz has not stipulated to the validity, enforceability and infringement of the earliest-expiring patents. (Sandoz Opp'n Br. at 17.) This reading of the Federal Circuit's opinion is at best simplistic and at worst misleading. In Janssen, the first applicant, Teva, had made a Paragraph III certification to the earliest-expiring patent and, like Apotex, could not launch prior to its expiration. The significance of Apotex's stipulation was that it placed Apotex in the same position as Teva with respect to the earliest-expiring patent. Therefore, "Apotex [was] excluded

from the market by Teva's 180-day exclusivity period – a period which Teva [was] entitled to under the Hatch-Waxman Act." Janssen, 540 F.3d at 1361. Here, Sandoz has made Paragraph III certifications to the 2013 patents. A Paragraph III certification is an official statement to FDA that Sandoz is not challenging the 2013 patents and is not seeking FDA approval until the 2013 patents expire. See 21 U.S.C. § 355(j)(2)(A)(vii)(III). Sandoz has therefore affirmatively put itself *in exactly the same situation* as Apotex did in Janssen, and Sandoz is similarly excluded from the market by Endo's exclusivity period. The holding in Janssen is directly applicable and controlling.

B. Sandoz's Claim of Possible Exclusion from Market Entry until 2020 Is Pure Speculation and Cannot Create the Controversy Required to Establish Standing

Sandoz claims that unless it is allowed to maintain its declaratory judgment counterclaims, "Endo may delay entering the market up until the day before the expiration of the '780 patent." (Sandoz Opp'n Br. at 10.) Sandoz speculates that Endo might "park" its exclusivity period and bar any subsequent applicant from entering the market. Id. Again, however, the Federal Circuit considered and rejected the same argument. Janssen, 540 F.3d at 1362-63. Having reviewed Apotex's assertion that "Teva may indefinitely delay launching for various reasons," id. at 1362, the court held that "a possible delay in the future of a first Paragraph IV ANDA filer in launching its generic product does not give rise to declaratory judgment jurisdiction." Id. at 1363.

Sandoz also speculates that Endo could "lose . . . its challenge against the '775 patent, while Sandoz will prevail." (Sandoz Opp'n Br. at 20.) As Genzyme aptly explained in its opening brief, however, this scenario is unlikely in the extreme. (Genzyme Mot. to Dismiss at 12-13.) First, if either Endo or Sandoz prevails on their invalidity defense, both parties win.

Sandoz's speculation requires, therefore, that (1) the patent is held valid and enforceable, (2) Sandoz is held not to infringe, and (3) Endo is held to infringe. The likelihood of all of these events occurring is virtually nonexistent because this case is essentially about the validity of claim 22 of the '775 patent and the infringement issues for Sandoz are near-identical to the issues for Endo. There is no remotely realistic litigation outcome that could prohibit Endo from marketing its product while allowing Sandoz to market its product.

To give rise to a justiciable Article III case or controversy, the alleged harm must be "'concrete' and 'actual or imminent,' not 'conjectural' or 'hypothetical.'" Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 103 (1998). Sandoz's speculations about litigation outcomes is no more than conjecture – an unfounded and unlikely conjecture at that.

C. Sandoz Improperly Dismisses the Possibility That Other Forfeiture Events Might Occur

Sandoz states that "Endo is not likely to incur any of the other statutory forfeiture events" and that "[t]he only forfeiture event that is of relevance here is the failure to market provision, which only Sandoz can trigger through litigation." (Sandoz Opp'n Br. at 21.) These assertions are conclusory and untrue. The occurrence of any one of numerous possible events can lead to the forfeiture of a first applicant's 180-day exclusivity period, including: (1) the first applicant's failure to market its drug; (2) the first applicant's withdrawal of its ANDA; (3) the first applicant's withdrawal or amendment of its Paragraph IV certification to the patent(s) on which exclusivity is based; (4) the first applicant's failure to obtain tentative approval of its ANDA by FDA within 30 months of the ANDA filing; (5) a court rendering a final decision that the first applicant has entered into an agreement with the NDA holder or another ANDA applicant that violates antitrust laws; and (6) the expiry of all of the patents that form the basis of exclusivity.

See 21 U.S.C. § 355(j)(5)(D)(i). Any of these events could potentially occur here between now and August 2013 for a variety of reasons, including changing economic conditions, shifting business priorities and any of a number of compliance and regulatory hurdles.

Moreover, at least one of these events, the applicant's failure to obtain tentative approval by FDA, rests largely in the hands of FDA and is outside Endo's direct control. Sandoz itself has recognized that "[t]entative approval is left up to the FDA." (Sandoz Opp'n Br. at 21.) Given this uncertainty, Sandoz's alleged harm is too speculative to give rise to an Article III case or controversy. See Steel Co., 523 U.S. at 103.

D. *Dey* Provides No Support for Sandoz's Position

Sandoz asserts that its "situation is analogous to the facts in Dey." (Sandoz Opp'n Br. at 19.) But even a cursory examination of the district court's opinion reveals the crucial difference between Dey on the one hand, and Janssen and this case on the other: "[U]nlike Apotex in the Janssen case, Dey has not precluded itself from going to market prior to the primary ANDA filer . . . . [I]n the instant case, the Court finds nothing equivalent to Apotex's stipulation . . . ." Dey, L.P. v. Sepracor, Inc., 595 F. Supp. 2d 355, 362 (D. Del. 2009). The court therefore concluded that, "unlike as in Janssen, if Dey were to prevail on its declaratory judgment action, the sole effect would not be to simply destroy [the first applicant's] exclusivity period. Rather, Dey could also potentially go to market well in advance of August 2012, the earliest date that [the first applicant] could go to market . . . ." Id. Here, of course, Sandoz's Paragraph III certifications to the 2013 patents bar Sandoz from entering the market prior to the earliest date that Endo can enter. Sandoz repeatedly states or suggests that prevailing on its counterclaims would allow Sandoz to bring a generic Renagel product to market before Endo. This repeated

inference is incorrect; Endo and Sandoz share an identical patent certification strategy. Far from supporting Sandoz's position, therefore, Dey appropriately follows Janssen and further supports Genzyme's motion to dismiss Sandoz's declaratory judgment counterclaims.

E. Sandoz Is Wrong about the Applicability of *Caraco* to Both Pre- and Post-MMA ANDAs

Sandoz casually attempts to dismiss Endo's argument regarding the inapplicability of Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd., 527 F.3d 1278 (Fed. Cir. 2008). (Sandoz Opp'n Br. at 18 n.13.) Caraco does not apply here because, among other reasons, the majority's holding was expressly tied to the pre-MMA Hatch-Waxman Act while Endo's ANDA was filed post-MMA and subject to the numerous forfeiture events in the MMA. Sandoz contends that the Federal Circuit in footnote 4 stated that its holding applied to both pre- and post-MMA ANDAs. Id. Sandoz is wrong.

Footnote 4 in Caraco reads as follows:

> The discussion here refers to the "failure to market" provision of the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(D), under which the first Paragraph IV ANDA filer can forfeit its 180-day exclusivity period by failing to market its generic drug. Section 355(j)(5)(D) replaced the 180-day exclusivity period triggering provisions that are applicable to this case, i.e. 21 U.S.C. § 355(j)(5)(B)(iv) (2000), including the court-judgment trigger. . . . Although the legislative discussion here refers to the amended 180-day provisions, this distinction is inconsequential because under both the original and amended 180-day provisions, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed. Thus, Senator Kennedy's remarks concerning the brand name drug company's incentive to delay such court decisions are equally applicable to this case.

Caraco, 527 F.3d at 1286 n.4. Thus, the court was simply explaining that a specific passage in the legislative discussion about the post-MMA "court decision" provision is applicable to the pre-MMA version of the "court decision" provision.

Sandoz not only misreads the footnote but ignores the later part of the opinion where the court makes clear that its decision rested on the absence of the numerous and comprehensive post-MMA forfeiture provisions. Id. at 1296 n.14. The pre-MMA forfeiture provisions only provided for the triggering of the exclusivity period upon commercial marketing by the first applicant or upon a court decision against the Orange Book patents. Id. at 1283. The passage of the MMA, however, added numerous events that can lead to forfeiture of the exclusivity period. See 21 U.S.C. § 355(j)(5)(D). Therefore, unlike under the post-MMA provisions governing this case, under the pre-MMA provisions governing Caraco it could not "plausibly be argued that [the first applicant] may nevertheless forfeit its exclusivity period." Caraco, 527 F.3d at 1296 n.14.

II. SANDOZ GROSSLY MISCHARACTERIZES THE PURPOSE AND IMPORTANCE OF THE 180-DAY EXCLUSIVITY PERIOD

Displaying a healthy dose of *chutzpa*, Sandoz asserts that "it has acted in the spirit of the Hatch-Waxman statute, while . . . Endo ha[s] acted to stifle competition." (Sandoz Opp'n Br. at 21.) The exact opposite is true. As Sandoz well knows, the 180-day exclusivity period is a vital component of the Hatch-Waxman framework that Congress put in place to encourage generic competition to expensive brand name drugs. See Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1075 (D.C. Cir. 1998); Sanofi-Aventis US LLC v. Sandoz, Inc., No. 07-2762, 2009 U.S. Dist. LEXIS 56453, at *12 (D.N.J. July 1, 2009) (attached as Ex. A). The promise of a relatively short marketing exclusivity period incentivizes generic companies to challenge brand companies' patents and to develop and bring to market generic alternatives to brand drugs. "[The 180-day] exclusivity [period] is valuable, [and was] designed to compensate manufacturers for research and development costs as well as the risk of litigation from patent holders." Teva Pharms. USA,

Inc. v. Leavitt, 548 F.3d 103, 104 (D.C. Cir. 2008). The exclusivity period allows generic drug companies to recoup their investments in research and development and the costs associated with prolonged and expensive patent litigation. See id.; Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26, 29 (D.D.C. 2006) (recognizing that Congress provided generic companies with the "critical incentive" of "a 180 day period of exclusivity during which no other generic version of the drug can be approved").

Here, Endo did exactly as Congress intended and committed its resources and know-how to quickly develop a generic version of Renagel. Endo won the race, defeating Sandoz and several other generic companies, to be the first generic applicant and thereby *earned* its right to the 180-day exclusivity period. Sandoz, on the contrary, is improperly attempting to use court procedures to destroy Endo's exclusivity and attain the benefits of early market entry without having done the work required to be the first applicant. It is Sandoz, therefore, that is attempting to undermine the incentive structure in the Hatch-Waxman Act that Congress established to encourage prompt Paragraph IV patent challenges and early generic entry.

CONCLUSION

For the foregoing reasons, and the reasons stated in Endo's and Genzyme's opening briefs, the Court should grant Genzyme's motion and dismiss Counts III and IV of Sandoz's counterclaims for declaratory judgment of noninfringement and invalidity of the '780 patent.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on January 22, 2010, I caused the foregoing to be filed with this Court's CM/ECF system for service on all record counsel.

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